Citation:

Mennella JA, Beauchamp GK. The transfer of alcohol to human milk. Effects on flavor and the infant's behavior. *N Engl J Med.* 1991 Oct 3; 325 (14): 981-985.

PubMed ID: 1886634

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine whether the ingestion of alcohol by a lactating woman altered the odor of her milk and whether exposure to a small amount of alcohol in the mother's milk had immediate effects on the behavior of the infant.

Inclusion Criteria:

Healthy, non-smoking women who were breast-feeding their infants and who had consumed at least one alcoholic beverage during lactation.

Exclusion Criteria:

- Mothers who do not comply with the nursing schedule
- Mothers who had difficulty expressing milk.

Description of Study Protocol:

Recruitment

University of Pennsylvania and La Leche groups

Design

- Cohort study. Twelve lactating women and their infants were tested on two days separated by an interval of one week. On each testing day, the mother expressed a small quantity of breast milk and then drank either orange juice or orange juice containing a small quantity of ethanol (0.3g per kg of body weight)
- Additional milk samples were obtained at fixed intervals after the ingestion of the beverage and analyzed to determine their ethanol content. The samples were also evaluated by a panel

of adults to determine whether any difference in the odor of the milk was detectable after alcohol ingestion. The infants were weighed before and after nursing to assess the amount of milk they ingested, and their behavior during breast-feeding was monitored by videotape.

Dietary Intake/Dietary Assessment Methodology

Each woman estimated the number and type of alcoholic drinks she consumed both during pregnancy (range, zero to nine drinks per nine months) and during lactation (range, 0.5 to 20 drinks per month).

Blinding Used

Six to eight panelists, blinded to the conditions under which the milk was collected, evaluated pairs of milk samples.

Intervention

Not applicable.

Statistical Analysis

A Friedman two-way analysis of variance by ranks was performed to determine whether there was a significant association between the time a milk sample was collected, and the panelists' choice of a sample as smelling "more like alcohol" or "stronger".

Data Collection Summary:

Timing of Measurements

Twelve lactating women and their infants were tested on two days separated by an interval of one week.

Dependent Variables

- Odor of milk
- Immediate effects on the behavior of the infant.

Independent Variables

Ingestion of alcohol by a lactating woman

Control Variables

None.

Description of Actual Data Sample:

- *Initial N:* 14 mother-infant pairs
- *Attrition (final N):* 12 mother-infant pairs
- *Age:*
  - Women aged 21-38 years (median, 30)
  - Infants (eight girls, four boys) aged 25-216 days (median, 120 days)
- *Ethnicity:* Not mentioned
- *Other relevant demographics:* Not mentioned

- *Anthropometrics:* Not mentioned
- *Location:* Philadelphia, PA.

Summary of Results:

Effect of Maternal Alcohol Consumption on the Feeding Behavior of Nursing Infants

Variable	Non-alcoholic beverage	Alcohol
Total amount of milk consumed (ml)	156.4±8.2	120.4±9.5
Total time attached to nipple (minutes)	28.6±7.7	28.2±7.3
Number of feedings	2.5±0.2	2.2±0.2
Mean number of sucks per feeding	307.1±56.4	352.3±64.8
Minute 1	58.4±5.9	67.0±6.5
Minute 2	56.2±6.5	61.2±5.4
Minute 3	49.8±5.8	58.0±4.9
≥Minute 4	142.7±38.2	166.1±48.0

Author Conclusion:

Short-term alcohol consumption by nursing mothers has an immediate effect on the sensory characteristics (odor) of their milk and the feeding behavior of their infants.

Reviewer Comments:

None.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes

3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	N/A
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A

3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A

6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes

10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes